REMARKS

STATUS OF THE CLAIMS

Claims 1, 5-11, 14-16, 19, 22-24, 31, 32 and 34-37 were pending as shown in the paper filed May 24, 2005. Pursuant to an election of species requirement, claims 3-6, 21, 22 and 31-37 have been withdrawn from consideration. Thus, claims 1, 5-11, 14-16, 19, 22-24, 31, 32 and 34-37 are pending and claims 1, 7-11, 14-16, 23 and 24 are under active examination.

Because claim 31 (which was amended in the previous response) has been withdrawn from consideration, the rejection of this claim has not been reiterated. However, Applicants again note that upon indication that generic claim 1 is allowable, the claims withdrawn pursuant to the election of species requirement will be examined.

REQUEST TO WITHDRAW FINALITY

Applicants respectfully request that the Office withdraw the finality of this Office Action and issue another non-final Office Action in this case. This request is made because the newly presented rejections based on U.S. Patent No. 5,660,873 (hereinafter "Nikolaychik") were not necessitated by Applicants' previous amendments.

As indicated in M.P.E.P. 706.07(a), final rejection is not proper when it is neither necessitated by Applicants' amendments nor based on information submitted in an IDS. In the pending case, Applicants' previous amendments made explicit what was previously implicit. Therefore, there is absolutely no reason that the rejections newly presented in this Final Office Action could not have been made previously. In other words, Applicants' amendments did **not** necessitate the newly presented rejections. Accordingly, Applicants herein request that the outstanding Office Action be considered non-final and this response treated accordingly.

REJECTIONS WITHDRAWN

Applicants note with appreciation that the rejection under 35 U.S.C. §§ 102(e)/103 based on U.S. Patent No. 6,231,590 (hereinafter "Slaikeu"), alone or in combination with U.S. Patent No. 5,891,192 (hereinafter "Murayama") or U.S. Patent No. 6,256,979 (hereinafter "Nikolchev") have been withdrawn.

35 U.S.C. § 103

Claims 1, 7, 8 and 11 were newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over Nikolaychik. (Final Office Action, paragraph 2). Claim 14 was rejected as allegedly obvious over Nikolaychik in view of Slaikeu. (Final Office Action, paragraph 4). Claim 15 was

rejected as allegedly obvious over Nikolaychik in view of Murayama. (Final Office Action, paragraph 4). Claim 16 was rejected as allegedly obvious over Nikolaychik in view of Nikolchev. (Final Office Action, paragraph 6).

In addition, claims 1, 7, 8, 9, 10, 23 and 24 were again rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,690,666 (hereinafter "Berenstein") in view of U.S. Patent No. 4,414,976 (hereinafter "Schwarz"). (Final Office Action, paragraph 3).

Applicant addresses the rejections in turn.

Nikolaychik

As noted above, claims 1, 7, 8, 11 and 14-16 were newly rejected as allegedly obvious over Nikolaychik alone or in combination with Slaikeu, Murayama or Nikolchev.

Nikolaychik was cited for allegedly disclosing a "composition consisting of a vaso-occlusive member and a bioactive material of fibrin and Factor XIII." *See,* paragraph 2 of the Final Office Action, citing col. 5, lines 21-33 of Nikolaychik. It was then asserted that Nikolaychik "discloses the claimed invention except for the vaso-occlusive member being a coil or a filter." *Id.*

In fact, Nikolaychik teaches absolutely nothing about vaso-occlusive members, let alone vaso-occlusive filters or coils as claimed. Rather, Nikolaychik relates to the opposite of vaso-occlusive members, namely stents, which, unlike the claimed vaso-occlusive compositions (which are designed to occlude a blood vessel) are designed to keep blood vessels open (see, *e.g.*, col. 1, lines 27-55 and col. 3, lines 39-50, emphasis added):

> The use of stents to reopen or replace the blocked portion of the blood vessel can create complications. Stents can themselves induce partial or complete blocking of the blood vessel by triggering blood clotting in the vicinity of the stent. After implantation, the natural process of fibrin deposition on the stent occurs to initiate the healing process. The deposition of the fibrin in the presence of thrombin triggers platelet activation and the formation of a thrombus or embolus. Bound thrombin can also induce the formation of more fibrin on the stent, thereby narrowing the luminal area of the stent. The reduced luminal area can cause an embolism in the patient.
>
> Several approaches have been employed to overcome the complications associated with vascular stents. In one approach, an anticoagulant is administered to the patient to reduce the likelihood of clotting. ... In yet another approach, a fibrin coating is deposited on the stent before implantation to facilitate the healing process. Compared to stents implanted without a fibrin coating, the incorporation of a fibrin coating on an implanted stent reduces significantly the likelihood of blood vessel blockage after implantation. ...

> The present invention has several advantages over existing substrates to be implanted in a living body. The incorporation of a fibrin coating on substrates of the present invention creates a low risk of blood clot formation after implantation of the substrate. The fibrin coatings of the present invention further provide a suitable environment for seeding the substrate with endothelial cells to reduce the thrombogenicity of the substrate. ... Finally, the fibrin coatings of the present invention can contain a substantial amount of natured fibrin and a limited amount of denatured fibrin. The presence of natured fibrin in the coating reduces the thrombogenicity of the coating.

In other words, Nikolaychik is focused on reducing vaso-occlusive effects of the underlying stent substrate. As set forth in the Response filed November 21, 2002, a reference must be considered for everything it teaches as a whole a reference must be used for what it teaches as a whole. See, e.g., *In re Wesslau* 47 USPQ 391 (CCPA 1965) holding that "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." Thus, a reference must be taken for all that it teaches or suggests. See, e.g., *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 420 (Fed. Cir. 1986). Further, functional limitations in the claims must be evaluated and considered, just as any other claim limitation, for what is fairly conveyed to the skilled artisan in context. (See, e.g., MPEP 2173.05(g) Functional Limitations, Eighth Edition).

Here, when viewed as a whole, it is clear the Nikolaychik in no way teaches or suggests compositions that function to occlude the vasculature, as claimed by Applicant. (*See, also,* Dictionary definitions attached to Response filed November 21, 2002 of "stent" indicating that the function of a stent is to prevent occlusion). Indeed, the passage in Nikolaychik cited by the Examiner (namely col. 5, lines 21,33) relates to "prosthetic devices, such as stents" that are subject to shear forces because they are designed to keep blood flowing. Thus, when properly read in context, the "substrates" in Nikolaychik are not vaso-occlusive members of any sort but, instead, stents that function to prevent occlusion of a vessel.

The Office cannot ignore the fact that there is no motivation to look to Nikolaychik's stent coatings for use in vaso-occlusive compositions. Since Nikolaychik's disclosure is limited to stents, this reference fails to teach or suggest critical limitations of any of the pending claims. To somehow assert that the skilled artisan reading a patent entitled "Coating Intraluminal **Stents**" would be motivated to combine these stent coatings with known vaso-occlusive devices is

contrary to both the conventional use of the term stent and, moreover, contrary to Nikolaychik's own teachings.

When taken as a whole, Nikolaychik is directed to completely different devices with completely different functions than the compositions claimed by Applicants. In short, the skilled artisan would not (and indeed could not) have been motivated from Nikolaychik, alone or in combination with Slaikeu, Murayama, or Nikolchev, to arrive at the invention as claimed, because the proposed modification would destroy the intended function of Nikolaychik's stents.

Berenstein

Claims 1, 7, 8, 9, 10, 23 and 24 were again rejected as allegedly obvious over Berenstein in view of Schwarz. (Final Office Action, paragraph 3). Berenstein was again cited for allegedly disclosing a vaso-occlusive coil that is used with a tissue adhesive while Schwarz is cited for teaching that a surgical tissue adhesive can be made with Factor XIII, plasminogen activator or plasmin inhibitor in order to stimulate wound healing. *Id.* It was alleged that it would have been obvious to provide the device of Berenstein with the tissue adhesive of Schwarz in order to promote wound healing. *Id.*

Furthermore, in response to Applicants' previous arguments, the Examiner stated (Final Office Action, paragraph 8):

> Applicant argues that Berenstein cannot be combined with Schwarz since there is no suggestion to combine. The examiner maintains that one would be motivated to combine Schwarz with Berenstein, since Berenstein uses tissue adhesives (see abstract) and Schwarz teaches a tissue adhesive that is used in the vascular system to stimulate healing (col. 2, line 64 to column 3, line 7).

The Examiner has not addressed Applicants arguments, and supporting evidence, that the motivation and suggestion to combine are lacking because Berenstein and Schwarz teach different tissue adhesives and use them for different purposes.

In particular, the Examiner has not addressed the fact that Berenstein and Schwarz cannot reasonably be combined as set forth solely on the basis that both disclose "tissue adhesives." Berenstein's tissue adhesives are embolic cyanoacrylate resins (see, col. 5, line 66 to col. 6, line 6 of Berenstein), while Schwarz's tissue adhesives are proteins. There is nothing in Berenstein that suggests Factor VIII would be a useful embolic and nothing in Schwarz that suggests cyanoacrylate resins would be interchangeable with protein wound sealants. In other words, the term "tissue adhesive" is used by Berenstein and Schwarz to refer to entirely different materials.

When viewed in context there is absolutely no motivation within the references or art as a whole to combine them as suggested by the Examiner.

Nor has the Examiner addressed Applicants argument and evidence establishing that Schwarz's disclosure of using Factor VIII "in order to promote healing" cannot provide the motivation to combine the references as set forth by the Examiner. There is nothing in Berenstein about promoting healing. Indeed, Berenstein is about promoting vaso-occlusion and, accordingly, relates entirely to tissue adhesives comprising cyanoacrylate embolization resins. Similarly, there is nothing in Schwarz about cyanoacrylate resins specifically or about vaso-occlusive compositions generally.

It is plain that a skilled artisan would not have been motivated to substitute Schwarz's wound healing proteins (used to seal wounds) for Berenstein's cyanoacrylate reins (used to occlude vessels in combination with ultrasoft coils). Moreover, it is impermissible for the Office to ignore that the fact that Berenstein's cyanoacrylate resins are unrelated to Factor VIII and that these "tissue adhesives" are not only entirely different materials, but also serve an entirely different purpose than Schwarz's Factor VIII (embolization in conjunction with ultrasoft vaso-occlusive coils in Berenstein and would healing by itself in Schwarz).

In sum, a skilled artisan would never have thought to substitute a polymeric resin used for embolization with a protein used for sealing wounds. Therefore, the Office has not (and indeed cannot) meet its burden of showing the motivation to substitute Schwarz's protein wound healing material for Berenstein's embolizing polymeric resins lies in the cited references or art as a whole. As such, the rejection cannot stand.

CONCLUSION

For the reasons discussed above, Applicants submit that the claims are in condition for allowance and request early notification to that effect.

If the Examiner has any further issues or wishes to discuss any of the foregoing, he is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: September 26, 2005

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